

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

STEVE M. MCKEE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:06CV803
	)	
NOVARTIS PHARMACEUTICALS	)	
CORPORATION,	)	
	)	
Defendant.	)	

**RECOMMENDATION OF MAGISTRATE JUDGE ELIASON**

This case is before the Court on Defendant's motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). To survive such a motion, a plaintiff must first comply with Fed. R. Civ. P. 8(a)(2), which requires "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atlantic Corp. v. Twombly, \_\_ U.S. \_\_, 127 S. Ct. 1955, 1964 (2007)(quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)).

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true.

Twombly, 127 S. Ct. at 1964-65 (internal citations omitted). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the

complaint." Id. at 1969. Further, the Court must construe all factual allegations in the light most favorable to Plaintiff, Republican Party of North Carolina v. Martin, 980 F.2d 943, 952 (4th Cir. 1992).

### **Facts**

Defendant Novartis Pharmaceuticals Corporation ("Novartis") employed Plaintiff Steve McKee ("McKee") as a pharmaceutical sales representative from August 1990 until September 2003. (Compl. ¶ 2.) In his complaint, Plaintiff claims that the parties had an amicable employment relationship until early 2002, when Defendant promoted him to its Neuroscience Specialty Division. At that time, Plaintiff alleges that he was asked to promote the "off-label" use of a prescription drug, Trileptal, to psychiatrists and other physicians. (Compl. ¶ 3.) Off-label uses, as defined by Plaintiff, are "uses of a drug that have not been proven safe [ ] or effective by the Food and Drug Administration ('FDA')." (Id.) Under the Food, Drug and Cosmetic Act ("FDCA"), drug manufacturers are generally prohibited from marketing drugs for such uses. 21 U.S.C. § 331(z).

Trileptal, the drug in issue here, is only FDA-approved for the treatment of epilepsy. Nonetheless, Plaintiff alleges that "almost immediately following the drug's launch, Novartis initiated an aggressive off-label promotion campaign to promote the drug for uses in psychiatry, including the treatment of bi-polar disorder." (Compl. ¶ 10.) Because, according to Plaintiff's belief, there are no approved psychiatric indications for Trileptal, he contends that

Defendant's decision to target psychiatrists with promotional calls and materials was illegal.

Plaintiff allegedly told his Area Manager and other sales representatives that he was "uncomfortable" with promoting Trileptal off-label, chiefly because of his qualms regarding the "safety and efficacy" of using the drug in psychiatric settings. (Compl. ¶¶ 13, 22, and 24.) He also requested to be transferred out of the Neuroscience Division, but his request was denied. (Compl. ¶ 25.) Plaintiff claims that he continued to voice his concerns to his manager and refused to promote off-label use during the remainder of his employment at Novartis. (Id.) He specifically alleges that he "questioned the legality of Novartis' off-label promotion practices to his Area Manager and others" at a national sales meeting in January 2003, and that he believes that his manager communicated his concerns on the matter to "higher ups in the Company including a Novartis Regional Director." (Compl. ¶¶ 25-26.) Because of Plaintiff's continuing refusal to promote Trileptal for off-label use, his sales numbers declined. (Compl. ¶¶ 26-27.) As a result, Plaintiff's manager placed him on a Performance Improvement Plan in June 2003. In September 2003, Plaintiff's sales numbers remained low, and the company terminated him. Plaintiff claims, however, that his "refusal to illegally promote off-label uses of Trileptal and his repeated complaints and reporting of same" were the true reasons for his termination. (Compl. ¶ 27.) These actions, he contends, are protected under § 3730 of the False Claims Act ("FCA" or "the Act").

### Discussion

The FCA, 31 U.S.C. § 3729, *et seq.*, is specifically designed to counteract fraudulent billings to the Federal Government. It allows individuals to file lawsuits, known as *qui tam* actions<sup>1</sup>, against contractors who submit, or cause to be submitted, false or fraudulent claims to the government. These individuals, or relators, are typically persons with insider knowledge of false claims involving government spending programs such as healthcare and the military.

The relevant provisions of the False Claims Act were set out in Eberhardt v. Integrated Design & Const., Inc., 167 F.3d 861 (4th Cir. 1999). There the Fourth Circuit stated:

31 U.S.C.A. § 3729 creates liability for any person who presents false claims to the federal government for payment. Section 3730 allows a private person to bring a civil action on behalf of the Government for violations of section 3729 (i.e., a "*qui tam* action"). Section 3730(h)—sometimes called the "whistleblower" provision of the False Claims Act—"prevents the harassment, retaliation, or threatening of employees who assist in or bring *qui tam* actions." Zahodnick v. IBM Corp., 135 F.3d 911, 914 (4th Cir.1997). It provides:

Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or

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<sup>1</sup>*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning he "who pursues this action on our Lord the King's behalf as well as his own." Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 769 n.1 (2000). *Qui tam* provisions permit individuals to sue on behalf of the government in return for being paid a percentage of the recovery. Id.

assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

31 U.S.C.A. § 3730(h). This court has previously spoken to the issues relevant to the instant case. In Zahodnick, this court extracted three elements from section 3730(h) that constitute a *prima facie* case: "[A]n employee must prove that (1) he took acts in furtherance of a *qui tam* suit [i.e. engaged in 'protected activity']; (2) his employer knew of these acts; and (3) his employer discharged him as a result of these acts." Zahodnick, 135 F.3d at 914.

Id. at 866. In the present case, Plaintiff fails to plead sufficient facts to support a claim for retaliation.

First, Plaintiff has not shown that he engaged in protected activity in furtherance of a *qui tam* action under the FCA. Section 3730(h) only provides a cause of action for individuals who take certain steps toward a *qui tam* suit, "including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under" the FCA. 31 U.S.C. § 3730(h). Exactly which steps constitute protected conduct is a fact-specific inquiry. Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 186 (3d Cir. 2001). In many instances, appropriate steps include internal reporting or independent investigation of an employer's false or fraudulent claims to the government. Id. at 186-187. The ultimate question is whether the employee's actions were calculated, or reasonably could lead, to viable *qui tam* litigation. Zahodnick v. IBM Corp., 135 F.3d 911, 914 (4th Cir. 1997). Only those employees who seek to remedy false or fraudulent government claims are protected by § 3730; the Act does not encompass employee actions

opposing other forms of illegal activity. See McKenzie v. BellSouth Telecommunications, Inc., 219 F.3d 508, 517 (6th Cir. 2000) (no cause of action under § 3730 where plaintiff's complaints addressed the defrauding of consumers rather than fraud on the federal government); see also Eberhardt, 167 F.3d at 868. Thus, to constitute protected activity, internal reporting must go beyond simply urging an employer to comply with the law. It must establish a nexus to the FCA. Zahodnick, 135 F.3d at 914 ("[s]imply reporting his concern of a mischarging to the government to his supervisor" did not establish that plaintiff "was acting 'in furtherance of' a *qui tam* action.").

Here, however, Plaintiff alleges nothing to show that his sole action of refusing to promote Trileptal, because off-label usage could be illegal, was in furtherance of a *qui tam* suit. Specifically, he fails to demonstrate that his refusal constitutes an "investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section," namely § 3730.

At the January 24, 2007 hearing, Plaintiff admitted he never conducted an investigation relative to false claims, never reported concerns of alleged off-label promotion to the government, and never discussed a possible *qui tam* suit with anyone at Novartis. (Tr. at 47, 54, 27, 29.) He also testified that he heard a report

on National Public Radio ("NPR").<sup>2</sup> He conveyed to his supervisor that: "if Pfizer is being sued for what they're doing with Neurontin, and it's illegal, then its got to be illegal for us to do it with Trileptal." (Tr. at 25.) Plaintiff argues that because he knew that Medicare pays for prescriptions of Trileptal (Tr. at 18) and because the "Pfizer lawsuit," as it turns out, was a *qui tam* action, that this shows his refusal to promote off-label usage of Trileptal constitutes an investigation and report concerning false claims and also notified his employer that such was his concern. The Court disagrees. The stretch is simply too great. Plaintiff did not complain about, or even know he was complaining about, false claims, nor did he notify his employer of such. Plaintiff's concern was that if the government knew about the off-brand promotion, it would stop it (Tr. at 38), but this has nothing to do with a concern that someone was causing the federal government to pay false claims. Plaintiff seeks to conduct discovery in the hopes that maybe the employer independently made the connection. However, lawsuits must be based on more than speculation. Bell Atlantic, supra.

Plaintiff's internal complaints to his supervisor merely advised Defendant that its off-label promotion was illegal in some

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<sup>2</sup>Plaintiff's citation of McKenzie v. BellSouth Telecommunications, Inc., 219 F.3d 508 (6th Cir. 2000), is inapposite. There, the court said if the employee had delivered a newspaper article to the employer mentioning a fraud claim against the federal government, that might constitute notice. Here, Plaintiff did not convey the transcript of the NPR news item or even show it mentioned false claims.

capacity, and that he was uncomfortable promoting the drug that way. There is no indication that these vague reports of illegality were tied to submitting false claims for reimbursement to the government and could lead to a *qui tam* suit or that Plaintiff intended them to do so. (As will be seen, without this connection, nothing ties Plaintiff's actions or his subsequent termination to the FCA either.) In short, Plaintiff has not claimed that he complained about, or refused to participate in, the submission of false or fraudulent claims to the federal government. As such, he fails to meet the first element of his claim.

Because the first two elements heavily overlap, Plaintiff's inability to satisfy the first element adversely affects his ability to satisfy the second element, i.e., § 3730(h)'s notice requirement. In particular, Plaintiff fails to plead that his employer knew of any actions he took in furtherance of a *qui tam* suit, in no small part because Plaintiff has not shown that he took such actions in the first place.

An employee must complain about more than just illegal activity to put his employer on notice of potential *qui tam* litigation. As stated above, unless his complaints involve allegations of government-related fraud, the FCA is not implicated. U.S. ex rel. Yesudian v. Howard University, 153 F.3d 731, 742 (D.D.C. 1998)(the notice requirement must be tied to the kind of activity in which the plaintiff must be engaged to satisfy the first element).



Plaintiff, instead, asserts that "the critical question is whether, in accordance with the Fourth Circuit's holding in Eberhardt, McKee's complaints were sufficient to apprise Novartis that litigation was a 'reasonable possibility.'" (Pl.'s Supp. Br. at 1.) This summation ignores a crucial factor in the Eberhardt decision. That is, a plaintiff must do more than notify his employer that there a "reasonable possibility" of litigation in general. Rather, he must put his employer "on notice that a suit *under the False Claims Act* would be a reasonable possibility." 167 F.3d at 869 (emphasis added). This distinction is pivotal. Unless a plaintiff's complaints contain some level of specificity beyond assertions of mere illegality, an employer can do no more than guess at their basis. Such guesswork clearly cannot be equated to a "reasonable possibility" of *qui tam* litigation. While Plaintiff is correct that "an employee need not have actually filed a *qui tam* suit or even know about the protections of § 3730(h) in order to engage in protected activity," see Eberhardt, 167 F.3d at 867, the employee must implicate the FCA in some way in order to show notice. This does not require an employee to use the Act's legal terminology, but it does require that he make some allegation that his employer is defrauding the federal government, i.e., making false claims for reimbursement. An employee who does not or is unable to understand and communicate this concept - the crux of the FCA - cannot hope to take the kinds of actions protected by § 3730(h), let alone put his employer on notice of those actions.

In the present case, Plaintiff's alleged activity arguably put Defendant on notice of potential litigation. He repeatedly referred to Defendant's off-label promotion marketing practices as "illegal," complained of these practices to his supervisor, and refused to take part in the off-label promotion of Trileptal. By his own accounts, however, Plaintiff's doubts about the drug's "safety and efficacy" for psychiatric uses were his primary concern in taking these steps. (Tr. at 38.) Plaintiff does not contend that he ever mentioned the terms Medicare, Medicaid, fraud, or false claims in any of his complaints. Further, his only reference to government of any kind came in the form of a statement to his manager that "the Government would love to hear what we're doing." (Tr. at 31.) This statement encounters two stumbling blocks in the context of his FCA claim. First, Plaintiff fails to identify which government - federal, state, or local. This is significant since § 3730(h) only covers fraud against the federal government. Second, Plaintiff's references to the government in the context of off-label drug promotion could just as easily refer to Defendant's alleged endangerment of patient health as to Medicare or Medicaid fraud. Thus, Defendant was left guessing as to the basis for Plaintiff's complaints and accusations. Because Plaintiff's actions were insufficient to notify Defendant that a *qui tam* suit was the concern, he cannot satisfy the second element of his retaliatory discharge claim.

Even if Plaintiff could demonstrate (1) that he engaged in protected activity in furtherance of a *qui tam* suit, and (2) that Defendant had adequate notice of those acts, he still fails to allege sufficient facts to establish the third element of his claim. That is, he fails to show that there was a causal connection between his alleged protected activity and his termination. "The FCA's legislative history states that the employee must show that 'the retaliation was motivated at least in part by the employee's engaging in protected activity.'" McKenzie, 219 F.3d at 518 (quoting S. Rep. No. 99-345, at 35, reprinted in 1986 U.S.C.C.A.C. at 5300). Such a showing requires more than a conclusory statement alleging retaliation. U.S. ex rel. Karcelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 240 (1st Cir. 2004). As the Karcelas court noted:

even under the liberal pleading requirements of Rule 8(a), a plaintiff must "set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Gooley v. Mobil Oil Corp., 851 F.2d 513, 514 (1st Cir. 1988). Simply parroting the language of a statutory cause of action, without providing some factual support, is not sufficient to state a claim.

Id. Because the plaintiff in the instant case provides no factual support for his assertion that his termination resulted from protected activity, his retaliation claim cannot survive Defendant's motion.

Indeed, the facts alleged in the complaint support quite the opposite conclusion. Plaintiff admits that his refusal to promote

Trileptal led to his "declining performance" in the months preceding his termination. (Compl. ¶ 26.) Even after Plaintiff was placed on a Performance Improvement Plan in June 2003, his "Trileptal numbers did not improve and on September 19, 2003, Novartis terminated him for allegedly failing to make his sales goals." (Compl. ¶ 27.) Stated more accurately, Novartis terminated Plaintiff for *admittedly* failing to make his sales goals. Nothing links the termination to activity relating to the possible promotion of the submission of false claims to the federal government by medical providers based on Defendant's promotion of off-label prescriptions. As such, there is no factual basis for his subsequent conclusion that "[t]he real reason for the termination was McKee's refusal to illegally promote off-label uses of Trileptal and his repeated complaints and reporting of [the] same."<sup>3</sup> (Id.)

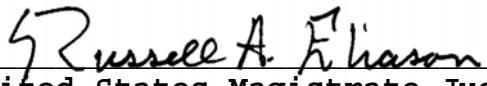
Because Plaintiff alleges insufficient facts to support a claim of retaliation under the FCA, this cause of action must be

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<sup>3</sup>Plaintiff may argue that, because his refusal to promote off-label uses of Trileptal led to his reduced sales, and his reduced sales led to his termination, his refusal did, in fact, lead to his termination. This argument, although logical, glosses over an important distinction. Mere refusal to participate in an illegal scheme, without more, and actually investigating or reporting that scheme because it involved false claims are quite different actions, and only the latter is covered by § 3730(h). See, e.g., Hardin v. DuPont Scandinavia, 731 F. Supp. 1202, 1205 (S.D.N.Y. 1990)(plaintiff failed to state a claim under § 3730(h) because her "alleged loss was the result of her refusal to participate in the alleged scheme, not the result of steps take in furtherance of the action"). Because Plaintiff never alleges facts which connect his vague complaints to his termination, he fails to satisfy the third element for a retaliation claim.

dismissed. In light of this decision, this Court should also decline supplemental jurisdiction under 28 U.S.C. § 1367(c)(3) over Plaintiff's state law claim for wrongful discharge in violation of public policy.

**IT IS THEREFORE RECOMMENDED** that Defendant's motion to dismiss (docket no. 10) be granted and that this action be dismissed.

  
United States Magistrate Judge

October 16, 2007